

REMARKS/ARGUMENTS

Claims 1-10 are pending. Claims 1-10 have been amended. Support for the amendments may at least be found in the specification, claims and figures as originally filed. No new matter has been entered as a result of the entry of these amendments.

The Examiner rejected claims 1-10 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

The Examiner rejected claims 1-10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner rejected claims 7-9 under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over U.S.P.N. 6,365,768 to Palladino.

The Examiner rejected claims 7-9 under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over U.S.P.N. 5,900,434 to Pyun et al.

The Examiner rejected claim 1-10 under 35 U.S.C. §103(a) as

being unpatentable over U.S.P.N. 6,593,363 to Suh et al. in view of the scholarly publication, Eloff, "Which extractant should be used for the screening and isolation of antimicrobial components from plants?", Journal of Ethnopharmacology, 60, pages 1-8 (1998).

Rejection under 35 U.S.C. 112, first paragraph

The Examiner rejected claims 1-10 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement.

Applicants have amended claims 1-10 and no longer recite the "prevention" of hepatitis.

In light of the foregoing amendments, Applicants respectfully request the Examiner withdraw the rejection of claims 1-10 under 35 U.S.C. §112, first paragraph, and find claims 1-10 allowable.

Rejection under 35 U.S.C. 112, second paragraph

The Examiner rejected claims 1-10 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants have amended claim 1 to provide antecedent basis for the terms "water extract" and "treatment", and deleted the term "prevention".

Applicants have amended claim 2 to provide the requested

clarification and provide antecedent basis for the term "ethanol insoluble part".

Applicants have amended claim 3 to provide the requested clarification and provide sought and provide antecedent basis for the term "fraction containing".

Applicants have amended claim 5 to provide the requested clarification and provide antecedent basis for the term "final concentration".

Applicants have amended claim 6 to provide the requested clarification and provide antecedent basis for the term "final concentration".

Applicants have amended claims 7-10 to provide the requested clarification.

In light of the foregoing amendments, Applicants respectfully request the Examiner withdraw the rejection of claims 1-10 under 35 U.S.C. 112, second paragraph, and find claims 1-10 allowable.

Rejections under 35 U.S.C. 102(b)/103(a)

The Examiner rejected claims 7-9 under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over U.S.P.N. 6,365,768 to Palladino.

In framing the present rejection, the Examiner asserted in part that Palladino teach using an extract from *Acanthopanax koreanum* to

inhibit Tumor Necrosis Factor- α , which can be attributed to viral infections such as hepatitis viruses and cirrhosis. Palladino teaches that acanthoic acid is a suspected effector of both Interleukin-a and TNF- α .

However, one of ordinary skill in the art, as well as Palladino, recognize that acanthoic acid is a hydrophobic compound and sparingly soluble in water. The solubility of acanthoic acid is reported to be sparingly soluble at a pH 7, the pH of water, as reported in Registry No. 119290-87-8 of the Chemical Abstracts Series ("CAS") for acanthoic acid. The CAS abstract of acanthoic acid is cited in a Supplemental Information Disclosure Statement submitted herewith by the Applicant. When extracting *Acanthopanax koreanum* with water, acanthoic acid is not extracted. In all of the examples taught by Palladino, Palladino does not extract acanthoic acid using water (See col. 20, l. 33-col. 25, l. 22; col. 27, l. 14-col. 38, l. 10; col. 44, l. 23-col. 51, l. 63). Based on the teachings of Palladino, one of ordinary skill in the art would anticipate that the water extract obtained by treating the root or stem of *Acanthopanax koreanum* with water does not contain acanthoic acid and thus does not exhibit a TNF- α inhibitory effect. Palladino actually teaches away from using water and thus cannot anticipate the subject matter of Applicants' claims 1-10.

With regard to the rejection under 35 U.S.C. 103(a), Palladino

does not teach, suggest or provide the requisite motivation to modify its teachings and achieve the subject matter recited in Applicants' claims 1-10. Palladino teaches away from using water to extract acanthoic acid by treating the root or stem of *Acanthopanax koreanum* with water. In addition, Palladino cannot provide the suggestion to use water as claimed by Applicant as the preferred methods of synthesis and every example taught by Palladino fails to use water (See col. 20, l. 33-col. 25, l. 22; col. 27, l. 14-col. 38, l. 10; col. 44, l. 23-col. 51, l. 63). Moreover, Palladino cannot provide the requisite motivation to modify its teachings to achieve the claimed subject matter recited in Applicants' claims 1-10 for these very same reasons. Palladino does not consider using water to extract acanthoic acid by treating the root or stem of *Acanthopanax koreanum* with water, because acanthoic acid would not be extracted by the water. Therefore, Palladino cannot motivate one of ordinary skill in the art to treat the root or stem of *Acanthopanax koreanum* with water to produce an extract exhibiting a TNF- α inhibitory effect.

Moreover, one of ordinary skill in the art recognizes that organic compounds exhibiting pharmacological activity are hydrophobic. When one of ordinary skill in the art search for pharmacologically active compounds, organic solvents are typically utilized as organic compounds are not extracted when using water.

Pharmacologically active compounds that dissolve in organic solvents generally do not dissolve in water. Hence, compounds or extracts that are pharmacologically active and obtained using organic solvents generally do not exhibit that same activity when obtained using water. Palladino only teaches that acanthoic acid dissolved in an organic solvent is a suspected effector of both Interleukin- α and TNF- α . Consequently, one of ordinary skill, in light of the teachings of Palladino, in the art could not expect to treat the root or stem of *Acanthopanax koreanum* with water to produce an extract exhibiting a TNF- α inhibitory effect. Such results are not expected when reading Palladino. Applicants' unexpected results are supported at least at Tables 2-5 of Applicants' specification.

Palladino can neither anticipate nor render obvious the claimed subject matter recited in Applicants' claims 1-10. In light of the foregoing, Applicants respectfully request the Examiner withdraw the rejections under 35 U.S.C. §§102(b)/103(a) and find claims 1-10 allowable over Palladino.

The Examiner rejected claims 7-9 under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over U.S.P.N. 5,900,434 to Pyun et al.

In framing the present rejection, the Examiner asserted in part that Pyun et al teach using an extract from *Acanthopanax koreanum* to

inhibit Tumor Necrosis Factor- α , which can be attributed to viral infections such as hepatitis viruses and cirrhosis. Pyun et al teaches that acanthoic acid is a suspected effector of both Interleukin-a and TNF- α .

However, one of ordinary skill in the art, as well as Pyun et al., recognize that acanthoic acid is a hydrophobic compound and sparingly soluble in water. When extracting *Acanthopanax koreanum* with water, acanthoic acid is not extracted. In all of the examples taught by Pyun, Pyun et al. does not extract acanthoic acid using water (See col. 3, l. 50-col. 4, l. 3; col. 4, l. 63-col. 13, l. 22). Based on the teachings of Pyun et al., one of ordinary skill in the art would anticipate that the water extract obtained by treating the root or stem of *Acanthopanax koreanum* with water does not contain acanthoic acid and thus does not exhibit a TNF- α inhibitory effect. Pyun et al. actually teaches away from using water and thus cannot anticipate the subject matter of Applicants' claims 1-10.

With regard to the rejection under 35 U.S.C. 103(a), Pyun et al. does not teach, suggest or provide the requisite motivation to modify its teachings and achieve the subject matter recited in Applicants' claims 1-10. Pyun teaches away from using water to extract acanthoic acid by treating the root or stem of *Acanthopanax koreanum* with water. In addition, Pyun et al. cannot provide the suggestion to use water as claimed by Applicant as the preferred methods of synthesis

and every example taught by Pyun fails to use water (See col. 3, l. 50-col. 4, l. 3; col. 4, l. 63-col. 13, l. 22). Moreover, Pyun et al. cannot provide the requisite motivation to modify its teachings to achieve the claimed subject matter recited in Applicants' claims 1-10 for these very same reasons. Pyun et al. does not consider using water to extract acanthoic acid by treating the root or stem of *Acanthopanax koreanum* with water, because acanthoic acid would not be extracted by the water. Therefore, Pyun et al. cannot motivate one of ordinary skill in the art to treat the root or stem of *Acanthopanax koreanum* with water to produce an extract exhibiting a TNF- α inhibitory effect.

Moreover, one of ordinary skill in the art recognizes that organic compounds exhibiting pharmacological activity are hydrophobic. When one of ordinary skill in the art search for pharmacologically active compounds, organic solvents are typically utilized as organic compounds are not extracted when using water. Pharmacologically active compounds that dissolve in organic solvents generally do not dissolve in water. Hence, compounds or extracts that are pharmacologically active and obtained using organic solvents generally do not exhibit that same activity when obtained using water. Pyun et al. only teaches that acanthoic acid dissolved in an organic solvent is a suspected effector of both Interleukin-a and TNF- α . Consequently, one of ordinary skill, in light of the

teachings of Pyun et al., in the art could not expect to treat the root or stem of *Acanthopanax koreanum* with water to produce an extract exhibiting a TNF- α inhibitory effect. Such results are not expected when reading Pyun et al. Applicants' unexpected results are supported at least at Tables 2-5 of Applicants' specification.

Pyun et al. can neither anticipate nor render obvious the claimed subject matter recited in Applicants' claims 1-10. In light of the foregoing, Applicants respectfully request the Examiner withdraw the rejections under 35 U.S.C. §§102(b)/103(a) and find claims 1-10 allowable over Pyun et al.

Rejections under 35 U.S.C. 103(a)

The Examiner rejected claim 1-10 under 35 U.S.C. §103(a) as being unpatentable over U.S.P.N. 6,593,363 to Suh et al. in view of the scholarly publication, Eloff, "Which extractant should be used for the screening and isolation of antimicrobial components from plants?", Journal of Ethnopharmacology, 60, pages 1-8 (1998).

In framing this rejection, the Examiner asserts the following:

"Suh et al. discloses extracting *Acanthopanax koreanum* with water and an alcohol. Suh et al. does not disclose extracting specifically with ethanol.

Eloff discloses that there are numerous extractants (such as methanol and ethanol or acetone, etc.) that can be used for extracting plant metabolites.

It would be obvious to substitute ethanol for methanol because they are both known in the art to have similar solvent characteristics. One of ordinary skill in the art would reasonably expect to use ethanol in Suh et al. because of the lower toxicity in ethanol than in methanol as shown in Eloff. Based on this reasonable expectation of success, one of ordinary skill in the art would be motivated to substitute ethanol for methanol in extracting *Acanthopanax koreanum*."

(Office action dated 10/31/05, page 6)

Applicants disagree with the Examiner's position. Suh et al. teaches extracting diterpene derivatives from *Acanthopanax koreanum* using alcohol, and not water (col. 2, l. 35-52; col. 13, l. 62-col. 36, l. 52). Throughout all of the examples, Suh et al. teaches initially dissolving the starting material in a solution composed in part of water and then washing an organic

layer with water. However, Suh et al. does not teach an extraction step or process using water. Suh et al. does not teach or suggest extraction using water. Moreover, Suh et al. does not provide the requisite motivation to one of ordinary skill in the art to modify its teachings in order to use water for extraction as such motivation is absent.

Eloff et al. explored the use of methanol/chloroform/water mixture and water for extracting *Anthocleista grandiflora* and *Combretum erythrophyllum*, two plants known to have antimicrobial activity. Although Eloff et al. explored the use of water for extraction, Eloff et al. did not recognize any benefits or advantages using water for extraction in its findings. In fact, Eloff et al. findings as disclosed in Table 1 and Section 3.6 of the text reflect that water extracted the fewest number of different components and inhibitors from both plants.

Eloff et al. does not teach or suggest using water for extraction, and cannot provide the requisite motivation to one of ordinary skill in the art to be combined with and modify the teachings of Suh et al. Such motivation is absent, especially in light of Eloff et al. findings which teaches water is not as useful as the other extractants examined.

One of ordinary skill in the art would not read the combination of Suh et al. in view of Eloff et al. and expect to

treat the root or stem of *Acanthopanax koreanum* with water to produce an extract exhibiting a TNF- α inhibitory effect. Such results achieved by the Applicants are not expected when reading Suh et al. in view of Eloff et al. Applicants' unexpected results are supported at least at Tables 2-5 of Applicants' specification.

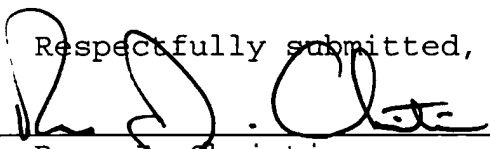
For these reasons, Suh et al. in view of Eloff et al. cannot render obvious the claimed subject matter recited in Applicants' claims 1-10. In light of the foregoing, Applicants respectfully request the Examiner withdraw the rejection under 35 U.S.C. §103(a) and find claims 1-10 allowable over Suh et al. in view of Eloff et al.

CONCLUSION

An earnest and thorough attempt has been made by the undersigned to resolve the outstanding issues in this case and place same in condition for allowance. If the Examiner has any questions or feels that a telephone or personal interview would be helpful in resolving any outstanding issues which remain in this application after consideration of this amendment, the Examiner is courteously invited to telephone the undersigned and the same would be gratefully appreciated.

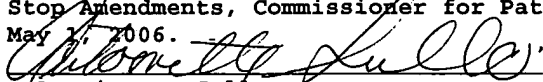
It is submitted that the claims herein patentably define over the art relied on by the Examiner and early allowance of same is courteously solicited.

If any additional fees are required in connection with this case, it is respectfully requested that they be charged to Deposit Account No. 02-0184.

Respectfully submitted,
By 
Ross J. Christie
Attorney for Applicants
Reg. No. 47,492
Tel: (203) 777-6628 x.116
Fax: (203) 865-0297

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I, Antoinette Sullo, hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail in an envelope addressed to: "Mail Stop Amendments, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313" on May 1, 2006.


Antoinette Sullo